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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,449	08/27/2003	Michael L. Robinson	28335/39524A	7321
4743 7590 09/12/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 09/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/650,449

Applicant(s)

ROBINSON ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 6, in so far as they are drawn to murine Hydin polynucleotide, classified in class 435, subclass 69.1, for example.
 - II. Claims 1 and 6, in so far as they are drawn to human Hydin polynucleotide, classified in class 435, subclass 69.1, for example.
 - III. Claims 2, 3 and 7, in so far as they are drawn to murine Hydin polypeptide, classified in class 530, subclass 350, for example.
 - IV. Claims 2, 4 and 7, in so far as they are drawn to human Hydin polypeptide, classified in class 530, subclass 350, for example.
 - V. Claim 5, in so far as it is drawn to an antibody to murine Hydin polypeptide, classified in class 530, subclass 387.1, for example.
 - VI. Claim 5, in so far as it is drawn to an antibody to human Hydin polypeptide, classified in class 530, subclass 387.1, for example.
 - VII. Claim 8, in so far as it is drawn to a method of detecting murine Hydin gene, classified in class 436, subclass 504, for example.
 - VIII. Claim 8, in so far as it is drawn to a method of detecting human Hydin gene, classified in class 436, subclass 504, for example.
 - IX. Claims 9-10, in so far as they are drawn to a method of detecting murine Hydin polypeptide, classified in class 435, subclass 7.1, for example.

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- X. Claims 9-10, in so far as they are drawn to a method of detecting human Hydin polypeptide, classified in class 435, subclass 7.1, for example.
 - XI. Claims 11-17, drawn to a method of detecting mutations in the human Hydin gene, classified in class 435, subclass 6, for example.
2. The inventions are distinct, each from the other because of the following reasons:
- The isolated polynucleotides that are inventions I to II, the isolated polypeptides that are inventions III to IV and the antibodies that are inventions V to VI are at least six different chemical compositions each of which can be made and used without each other. Each of these proteins, antibodies and nucleic acids are independent and distinct chemical compounds lacking either a common structural property which distinguishes them as a group from structurally related compounds of the prior art or which provides them with a common utility which is lacking from those prior art proteins or nucleic acids.
3. Inventions I to VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the polynucleotide of Group (I-II) and polypeptide of Group (III-IV) are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group (I-II) does not necessarily encode the polypeptide of Group (III-IV). Furthermore, the information provided by the polynucleotide of

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Group (I-II) can be used to make a materially different polypeptide than that of Group (III-IV). In addition, while a polypeptide of Group (III-IV) can be made by methods of using some, but not all, of the polynucleotides that fall within the scope of Group (I-II), it can also be recovered from a natural source using biochemical means, such as affinity chromatography, for example.

Furthermore, searching the inventions of Groups (I-II) and (III-IV) together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of Groups (I-II) and (III-IV) have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature and electronic databases. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, the scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above. As such, it would be burdensome to search the inventions of Groups (I-II) and (III-IV).

4. The polypeptides of Group (III-IV) and the antibodies of Group (V-VI) are patentably distinct for the following reasons: while the inventions of both Groups (III-IV) and (V-VI) are polypeptides, in this instance, the polypeptides of Group (III-IV) is a single chain molecule, whereas the polypeptide of Group (III-IV) encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including

framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptides of Group (III-IV) and the antibodies of Group (V-VI) are structurally distinct molecules; any relationship between a polypeptide of Group (III-IV) and an antibody of Group (V-VI) is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptides of Group (III-IV) are structurally unrelated large molecules which contain potentially hundreds of regions to which an antibody can bind, whereas the antibody of Group (V-VI) is defined in terms of its binding specificity to a small structure within the disclosed SEQ ID NO. Thus, immunization with the polypeptide of Group (III-IV) would result in the production of antibodies outside the scope of Group (III-IV). Furthermore, searching the inventions of Group (III-IV) and Groups (V-VI) would impose a serious search burden because both groups require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search would not necessarily determine novelty and unobviousness of the antibodies. Furthermore, antibodies which bind to an epitope of a polypeptide of Group (III-IV) may be known even if a polypeptide of Group (III-IV) is novel. In addition, the technical literature search for the polypeptides of Group (III-IV) and the antibodies of Group (V-VI) is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

5. The polynucleotide of Group (I-II) and the antibody of Group (V-VI) are patentably distinct for the following reasons: the antibody of Group (V-VI) includes, for example, IgG

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which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of Group (V-VI) which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group (I-II) will not encode an antibody of Group (V-VI), and an antibody of Group (V-VI) cannot be encoded by a polynucleotide of Group (I-II). Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups (I-II) and (V-VI) would impose a serious search burden since a search of the polynucleotide of Group (I-II) would not be used to determine the patentability of an antibody of Group (V-VI) and vice-versa.

6. Inventions VII to XI are unrelated as well. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these methods would be used together. The methods of Groups VII to XI are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different

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mode of operation. Each invention performs this function using structurally and functionally divergent material. Searching the inventions of Groups VII to XI together would impose serious search burden. The inventions of Groups VII to XI have a separate status in the art as shown by their different classification. Moreover, in the instant case, the searches for each claimed method are not coextensive. Prior art which teaches a method of nucleic acid hybridization would not necessarily be applicable to the methods of detecting of proteins, for example. For these reasons the Inventions VII to XI are patentably distinct.

7. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.


Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

September 7, 2007